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April 2, 2020

Via ECF

Hon. Paul W. Grimm
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 465A
Greenbelt, Maryland 20770

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

In accordance with the Court's paperless order dated April 1, 2020 (ECF No. 176), Defendants respectfully waive a substantive reply in support of their request for an indicative ruling for a 120-day extension of the May 12, 2020 premarket application deadline imposed in the Court's remedy order in light of the coronavirus outbreak. The request is unopposed (*see* ECF No. 177) and should be granted.

Defendants respectfully urge that the Court rule on their request by April 7, 2020, due to the need for certainty in light of the coronavirus outbreak and the upcoming May 12 deadline.¹ Defendants have conferred with Plaintiffs, who do not oppose Defendants' request for a ruling by April 7.

Defendants thank the Court for its attention to this matter.

¹ Multiple manufacturers who have requested extensions of the May 12 deadline have asked the FDA for an expedited determination on their requested extensions and have indicated that they intend to seek emergency relief from other federal courts absent an expedited determination. *See* Response to Notice, ECF No. 191, *Cigar Ass'n of Am. v. FDA*, No. 16-cv-1460 (D.D.C. Apr. 1, 2020); Mot. to Reopen & Reply, ECF Nos. 38 & 44, *Sanchez Icaza v. FDA*, No. 16-cv-21967 (S.D. Fla. Mar. 13, 2020 & Apr. 2, 2020).

Respectfully submitted,

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/s/ Garrett Coyle
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